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Edward J Lynch Duane Morris LLP One Market Spear Tower Suite 2000 San Francisco, CA 94105				
EXAMINER				
RAMANA, ANURADHA				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/620,154

Applicant(s)

TALABER ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33-40, 42-60, 63-79, 84-86 and 88-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-28, 59, 84-86, 88 and 107-113 is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-17, 19, 29-40, 42-50, 52-58, 60, 63-79, 89-106 and 114 is/are rejected.
- 7) ☒ Claim(s) 4-8, 18, 20 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/7/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 52, line 15: recitation of "the securing member" lacks antecedent basis.

In claim 54, line 17: recitation of "the securing element" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 9-11, 16-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dill (US 5,118,235).

Dill discloses a stabilizing element 10 having an anterior surface, a posterior surface and at least one bore 56 having a first opening in the anterior surface and a second opening in the posterior surface smaller than the first opening; a biased stopping member 80; a pin or "securing element" 14 having an elongated body 38 with a head 36 integral with the body, the head having a maximum diameter greater than the

smaller diameter configuration of the passageway; and a curved lip or "biased stopping member" 80 that defines a reversibly expandable passageway (Figs. 2 and 7, col. 3, lines 33-68 and col. 4, lines 1-16).

Regarding the recitation, "An orthopedic implant assembly" it is noted that if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation") (per MPEP 2111.02).

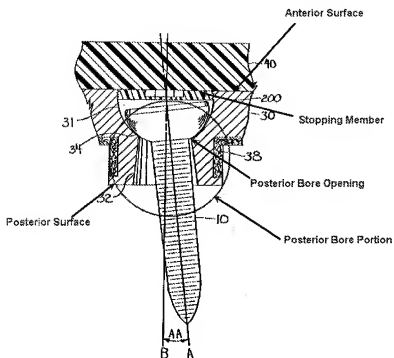
Claims 29, 31, 33-36, 42-47, 60, 102, 106 and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodorek (US 5,534,032).

Hodorek discloses an orthopedic attachment assembly including: an elongated securing member 10 having an enlarged integral portion 11 with a curved posterior surface; an attachment member 30 having an anterior surface, a posterior surface and at least one bore extending from the anterior surface to the posterior surface; a bore having an anterior bore portion and a posterior bore portion with a posterior bore opening having at least one transverse dimension smaller than a transverse dimension of the enlarged integral portion of the securing member; and a stopping member or "biased stopping member" 200 which reduces a transverse configuration of the bore when placed in the bore and defines or demarcates the posterior bore portion from the anterior bore portion (Fig. 7 and col. 5, lines 22-37). It is noted that stopping member is biased in that it has threads that engage threads in member 30.

Regarding claim 45, it is noted that a fixation element such as a plate conforms to the surface of the underlying bone in order to serve its intended purpose and thus would have a curved surface.

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Please refer marked up Fig. 7 from Hodorek below.

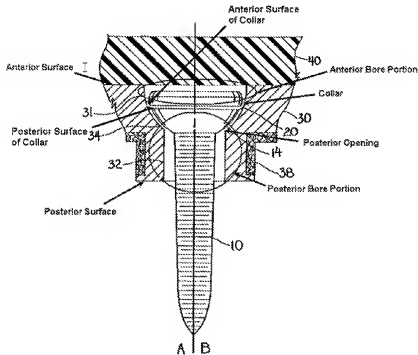


Using an alternate interpretation, claims 29-31, 33-37, 39-40, 42-48, 60, 89-95, 102, 105 and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodorek (US 5,534,032).

Hodorek discloses an orthopedic implant assembly including: a stabilizing element 30 having an anterior surface, a posterior surface and at least one bore extending through the stabilizing element from the anterior surface to the posterior surface; a posterior bore portion having a posterior opening with a transverse dimension smaller than a transverse dimension of the anterior bore portion; a securing element 10 having an enlarged integral portion 11; a radially deflectable or longitudinally deflectable member 20 including a raised portion or collar (Fig. 6 and col. 3, lines 6-40). Please refer marked up Fig. 6 on the following page. Note that member 20 is resilient and is therefore capable of being radially as well as longitudinally deflectable.

Regarding claim 45, it is noted that a fixation element such as a plate conforms to the surface of the underlying bone in order to serve its intended purpose and thus would have a curved surface.

Regarding claim 105, it is noted that member 20 is capable of returning to the first configuration after passage of the enlarged integral portion of the securing member. It is noted that Applicant's are not claiming that the securing member has to pass through the biased stopping member in order for orthopedic implant to be assembled.

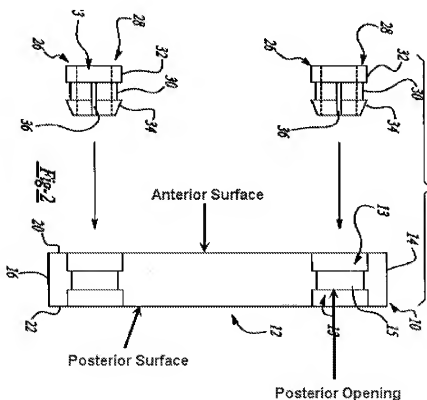


Claims 29, 31, 36, 42-48, 50 and 89-105 are rejected under 35 U.S.C. 102(e) as being anticipated by Richelsoph (US 6,017,345).

Richelsoph discloses an orthopedic implant assembly including: a plate or "stabilizing element" 12 having an anterior surface and a posterior surface; a bore extending from the anterior surface to the posterior surface, the bore having an anterior bore portion and a posterior bore portion with a posterior opening with a transverse dimension smaller than a transverse dimension of the anterior bore portion (the stepped

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bore presents an opening or aperture at each step); an insert or "stopping member" or "resilient member" 28 having a biased collar disposed within the bore, the insert defining a reversible expandable passageway wherein a second transverse or expanded configuration is larger than a transverse dimension of a first or unexpanded or normal biased configuration; and a screw or "securing element" 40 having an enlarged portion 54 is slidably disposed in the bore of the stabilizing element (Figs. 2-17, col. 4, lines 32-67 and col. 5, lines 1-67). See marked up Fig. 2 from Richelsoph below.



Regarding claim 45, a fixation element such as a plate conforms to the surface of the underlying bone in order to serve its intended purpose and thus would have a curved surface.

Regarding claim 89, enlarged integral portion has a maximum transverse dimension defined by head 50, greater than a transverse dimension of the posterior opening of the posterior bore portion.

Regarding claims 94 and 96, insert 28 is longitudinally or radially deflectable upon application of a suitable force by virtue of being compressible.

Regarding claim 105, it is noted that insert 28 is capable of returning to the first configuration after passage of the enlarged integral portion of the securing member. It is noted that Applicant's are not claiming that the securing member has to pass through the biased stopping member in order for orthopedic implant to be assembled.

Claims 1, 10-17, 29, 31, 33, 36, 42-50, 52-53, 60, 63-79, 89-96, 99-103, 106 and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Estes (US 5,578,034).

Estes discloses an attachment component or stabilizing element 12 including: an elongated securing member 14 having a head with a maximum diameter defined by the enlarged head portion 20 and a smaller diameter portion connecting the enlarged head portion 20 to screw shaft 22; a bore 18, the bore having an anterior bore portion and a posterior bore portion, the posterior bore portion having at least one transverse dimension smaller than the transverse dimension of the enlarged integral portion of the securing member; a stopping member 16 which reduces a transverse configuration of the bore, to define at least in part the posterior bore portion to retain the enlarged integral portion of the securing member wherein the collar is formed of an elastically deformable or superelastic material (Fig. 1, col. 4, lines 36-67, col. 5 and col. 6, lines 1-46). See marked up Fig. 1 from Estes on the following page.

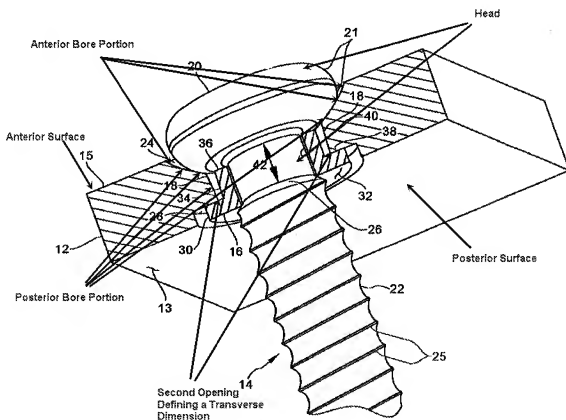
Regarding claims 14, 45 and 77, a fixation element such as a plate conforms to the surface of the underlying bone in order to serve its intended use and thus could have a curved surface.

The method steps of claims 52 and 53 are inherently performed when the Estes assembly is used for internal fixation of bone.

Regarding claims 69 and 70, the Examiner notes that the limitation "configured to expand the collar.....the collar passageway" and "configured to contact an anterior surface of the collar and deflect the collar away from a longitudinal axis of the collar passageway" is met by Estes, because the enlarged integral portion of the securing

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element or member is capable of expanding the collar if it is pushed through the collar. With regard to being "configured to" it has been held that the recitation that an element is adapted or configured to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodorek (US 5,534,032).

Hodorek discloses all elements of the claimed invention except for the stopping member being made of titanium or a superelastic material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed stopping member of titanium or a superelastic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein enhanced mechanical properties including fatigue endurance, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richelsoph (US 6,017,345).

Richelsoph discloses all elements of the claimed invention except for the stopping member being made of titanium or a superelastic material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed stopping member of titanium or a superelastic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein enhanced mechanical properties including fatigue endurance, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on July 3, 2007 have been fully considered.

Applicant's arguments with respect to the rejections of claims 60, 63-67, 73 and 89-95 as being anticipated by Estes (US 5,578,034) are not persuasive for the following reason. The bore of Estes has an anterior bore portion and a posterior bore portion as illustrated in marked up Fig. 1 from Estes on page. It is noted that the Examiner is interpreting the "anterior bore portion" to be a small portion of the bore close to the anterior surface of the plate with the rest of the bore defining the posterior bore portion. Further, the head of the securing member has two portions, an enlarged portion and a smooth portion connecting the enlarged portion to the screw shaft. Contrary to Applicant's arguments, Estes discloses Applicant's claimed invention as discussed in the rejections above and therefore anticipates the claims.

Allowable Subject Matter

The Examiner is withdrawing the allowability of claims 1-3, 9-17 and 19 due to new grounds of rejection made in this action. The Examiner sincerely apologizes for any inconvenience caused to the Applicant by this action.

Claims 52-58 would be allowable if the rejections under 35 U.S.C. 112 second paragraph set forth in this action are overcome.

Claims 4-8, 18, 20 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21-28, 59, 84-86, 88 and 107-113 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-

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4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
March 10, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3733